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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/996,438	11/20/2001	William Stefan Bess	5724-03-EJF	3857

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Evan J. Federman
Legal Division, Warner-Lambert Company
201 Tabor Road
Morris Plains, NJ 07950

EXAMINER	
JONES, DWAYNE C	
ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 04/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/996,438

Applicant(s)

BESS ET AL.

Examiner

Dwayne C. Jones

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on the amendment of 27DEC2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,32,33,35-37,39-42,44-50 and 54-56 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,32,33,35-37,39-42,44-50 and 54-56 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Status of Claims

1. Claims 1, 32-33, 35-37, 39-42, 44-50, and 54-56 are pending.
2. Claims 1, 32-33, 35-37, 39-42, 44-50, and 54-56 are rejected.
3. Claims 51-53 are cancelled as per the amendment of December 27, 2004.

Response to Arguments

4. Applicants' arguments filed December 27, 2004 have been fully considered but they are not persuasive with respect to Nichols et al. of WO 97/37689 as well as Keown et al. of WO 95/11034. Applicants allege that neither of the prior art references of Keown et al. nor Nichols et al. teach the claimed embodiments of Applicants invention as instantly claimed subject matter as presented in the amendment of December 27, 2004.

Claim Rejections - 35 USC § 103

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
6. The rejection of claims 1, 32-33, 35-37, 39-42, 44-50, and 54-56 under 35 U.S.C. 103 as being unpatentable over Keown et al. of WO 95/11034 is maintained for both the above-stated and reasons of record. The instant claims are composition claims that require the presence of the acid salt of a sympathomimetic amine and an

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amino polymer. Keown et al. also teach of a pharmaceutical composition, which contains a sympathomimetic agent, such as ephedrine, (as cited from the abstract). Applicants now attempt to limit the instantly claimed and previously known subject matter by amending the claims to further include "at least one additional active pharmaceutical ingredient." The prior art reference of Keown et al. specifically recite and teach of the following that the "composition of the invention may also comprise other active agents . . . such as acetylsalicylic acid . . . chromium picolinate", (see page 17, lines 20-26). In addition, Keown et al. also teach that this pharmaceutical composition contains various semi-permeable polymers that are known in the art such as those of, inter alia, U.S. Patent No. 3,546,142, (as cited on page 15 of Keown et al.). U.S. Patent No. 3,546,142 lists the amine-containing polymer of polydimethylaminoethyl methacrylate, (see column 2, lines 13-14). Accordingly, Keown et al. again render the instant composition claims obvious because the skilled artisan would have been motivated to select a known material based on its suitability for its intended use, which supported a prima facie obviousness determination in *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 65 USPQ 297 (1945). In addition, composition claims are not deemed to be limited by an "intended use", see *In re Hack* 114 USPQ 161. Accordingly, the prior art reference of Keown et al. do render the instant invention obvious because Keown et al. teach of a sympathomimetic amine, namely ephedrine.

7. The rejection of claims 1, 32-33, 35-37, 39-42, 44-50, and 54-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nichols et al. of WO 97/37689 is maintained for both the above-stated and reasons of record. Nichols et al. teach of a

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composition that contains a sympathomimetic amine with other compounds, which make it difficult or essentially infeasible to synthesize illegal drugs from the sympathomimetic amine compounds, (see page 4, lines 1-23). In addition, Nichols et al. teach of various denaturants, in particular amine-containing compounds and well as various polymers, that are used to make the pure sympathomimetic amine salt difficult or essentially infeasible to isolate. Nichols et al. do not specifically teach of an amino polymer. Applicants now attempt to limit the instantly claimed and previously known subject matter by amending the claims to further include "at least one additional active pharmaceutical ingredient." The prior art reference of Nichols et al. specifically recite and teach of the following that a "large collection of additional active ingredients may optionally be present in the sympathomimetic amine and inhibitor composition of the instant invention. The suitable categories of optional active ingredients that may be employed varies widely . . . [I]llustrative categories and specific examples of these optional active ingredients include . . . antitussives such as dextromethorphan . . . antihistamines such as chlorpheniramine maleate . . . antiasthmatic drugs . . . analgesics . . . non-steroidal anti-inflammatory drugs . . . and . . . expectorants", (see from page 21, line 26 to page 22, line 13). The skilled artisan would have been motivated to utilize the teachings of Nichols et al. to utilize other types of denaturants, especially when Nichols et al. teach of various denaturants, in particular amine-containing compounds and various types of polymer-containing compounds because the purpose of the denaturant is to make it difficult or essentially infeasible to synthesize illegal drugs from the sympathomimetic amine compounds. Nichols et al. also teach and provide explicit

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motivation to include other components such as "acrylic derivatives", (see page, lines 20-23). In view of this information, the skilled artisan would have been motivated to utilize the teachings of Nichols et al. to utilize other types of carriers and excipients and conventional ingredients that would render the instant invention obvious.

Obviousness-type Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 1, 32-33, 35-37, 39-42, 44-50, and 54-56 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-29 of U.S. Patent No. 6,359,011 in view of Nichols et al. of WO 97/37689. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are directed to salts of transition metals whereas U.S. Patent No. U.S. Patent No. 6,359,011 is directed to transition metal salts of iron, copper, cobalt, manganese, nickel and zinc.

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10. Nichols et al. teach of a composition that contains a sympathomimetic amine with other compounds, which make it difficult or essentially infeasible to synthesize illegal drugs from the sympathomimetic amine compounds, (see page 4, lines 1-23). In addition, Nichols et al. teach of various denaturants, in particular amine-containing compounds and well as various polymers, that are used to make the pure sympathomimetic amine salt difficult or essentially infeasible to isolate. Nichols et al. do not specifically teach of an amino polymer. Applicants now attempt to limit the instantly claimed and previously known subject matter by amending the claims to further include "at least one additional active pharmaceutical ingredient." The prior art reference of Nichols et al. specifically recite and teach of the following that a "large collection of additional active ingredients may optionally be present in the sympathomimetic amine and inhibitor composition of the instant invention. The suitable categories of optional active ingredients that may be employed varies widely . . . [I]llustrative categories and specific examples of these optional active ingredients include . . . antitussives such as dextromethorphan . . . antihistamines such as chlorpheniramine maleate . . . antiasthmatic drugs . . . analgesics . . . non-steroidal anti-inflammatory drugs . . . and . . . expectorants", (see from page 21, line 26 to page 22, line 13). The skilled artisan would have been motivated to utilize the teachings of Nichols et al. to utilize other types of denaturants, especially when Nichols et al. teach of various denaturants, in particular amine-containing compounds and various types of polymer-containing compounds because the purpose of the denaturant is to make it difficult or essentially infeasible to synthesize illegal drugs from the sympathomimetic amine compounds. Nichols et al.

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also teach and provide explicit motivation to include other components such as "acrylic derivatives", (see page, lines 20-23). In view of this information, the skilled artisan would have been motivated to utilize the teachings of Nichols et al. to utilize other types of carriers and excipients and conventional ingredients that would render the instant invention obvious. Clearly, the skilled artisan would have been motivated to combine these teachings especially since they are both directed to the very same purpose of making it infeasible to synthesize illegal drugs from the sympathomimetic amine compounds.

11. Claims 1, 32-33, 35-37, 39-42, 44-50, and 54-56 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-22, and 32-34 of copending Application No. 09/533,005. Although the conflicting claims are not identical, they are not patentably distinct from each other because both teach of a composition that contains inter alia, an amino polymer as well as a decongestant. In addition, applicant recites the word "comprising", which is open-claim language. It is held that "the word 'comprising' incorporates additional steps of procedures and does not exclude materials or processes not recited in the claim". *Gould v. Mossinghoff, Comr. Pats.*, (DCCD 1982) 215 USPQ 310.

12. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. C. Jones whose telephone number is (571) 272-0578. The examiner can normally be reached on Mondays, Tuesdays, Wednesdays; and Fridays from 8:30 am to 6:00 pm.

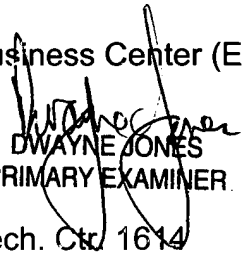
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, may be reached at (571) 272-0951. The official fax No. for correspondence is (571)-273-8300.

Also, please note that U.S. patents and U.S. patent application publications are no longer supplied with Office actions. Accordingly, the cited U.S. patents and patent application publications are available for download via the Office's PAIR, see <http://pair-direct.uspto.gov>. As an alternate source, all U.S. patents and patent application

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publications are available on the USPTO web site (www.uspto.gov), from the Office of Public Records and from commercial sources.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications may be obtained from Private PAIR only. For more information about PAIR system, see <http://pair-direct.uspto.gov> Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 1-866-217-9197 (toll free).


DWAYNE JONES
PRIMARY EXAMINER

Tech. Ctr. 1614
April 15, 2005